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Efficacy and acceptability of a new emotional and social mind group training programme for bulimia nervosa

Submission date
14/04/2009

Recruitment status
No longer recruiting

Registration date
29/05/2009

Overall study status
Completed

Last Edited
12/05/2015

Condition category
Mental and Behavioural Disorders

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Bulimia nervosa is an eating disorder and mental health condition. People who have bulimia try to control their weight by severely restricting the amount of food they eat, then binge eating and purging the food from their body by making themselves vomit or using laxatives. UK government guidelines suggest a talking therapy called cognitive behavioural therapy (CBT) as the first-line treatment for bulimia nervosa. However, a substantial proportion of those treated with CBT (60-70%) still suffer with symptoms at follow up. Our new intervention provides an innovative approach to help improve the outcome of patients with bulimia nervosa and related disorders, through addressing the underlying maintenance mechanisms rather than exclusively targeting the presenting symptoms of the disorder. The aim of this study was to test the effectiveness and acceptability of this new emotional and social mind group training programme for bulimia nervosa and related disorders.

Who can participate?
Patients aged 18 - 65 with bulimic disorders referred to our outpatient eating disorders service at the Maudsley Hospital, South London.

What does the study involve?
Participants were randomly allocated to attend either the new emotional and social mind group training programme or a group CBT programme for bulimic disorders.

What are the possible benefits and risks of participating?
The benefits of participating in the study included receiving an eating-disorder specific treatment delivered by experienced eating disorder therapists, regardless of which group of the study the participant was allocated to. Possible risks were that the new training programme was untested and thus not backed by evidence that it was effective.

Where is the study run from?
Institute of Psychiatry, Section of Eating Disorders and South London and Maudsley NHS Foundation Trust Eating Disorders Service, London, UK.

When is the study starting and how long is it expected to run for?
From June 2009 to January 2011.

Who is funding the study?
Swiss Anorexia Foundation (Switzerland).

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Study information

Scientific Title
A preliminary randomised controlled trial of the efficacy and acceptability of a new emotional and social mind group training programme versus standard cognitive behavioural group therapy for bulimia nervosa

Study objectives
A 17-session group based intervention emotional and social mind training (ESM) targeting the key maintenance variables for bulimia nervosa outlined above will be superior to a 17-session group-based standard cognitive behavioural therapy (CBT) programme for this group, in terms of achieving symptomatic improvement in bulimic symptoms and mood.

Subsidiary hypotheses:
1. Drop out will be lower in the ESM than the CBT group
2. Acceptability of treatment will be superior in the ESM group, compared with the CBT programme
3. ESM will be superior to the CBT programme in terms of the following variables, which will mediate or moderate symptom change:

3.1. Reducing intolerance of emotional distress (moderator)
3.2. Decreasing negative self-evaluation (mediator)
3.3. Increasing adaptive emotional expression and processing (mediator)
3.4. Increasing ability to regulate negative mood (mediator)
3.5. Reducing self-criticism (mediator)
3.6. Reducing negative beliefs about emotions (mediator)
3.7. Reducing rumination (mediator)
3.8. Reducing socially submissive behaviour (mediator)
3.9. Improving social cognition (mediator)

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Joint South London and Maudsley and Institute of Psychiatry NHS Research Ethics Committee, November 2008, ref: 08/H0807/83

Primary study design
Interventional

Study design
Single-centre two-arm single-blind randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Bulimia nervosa (BN)/eating disorder not otherwise specified (EDNOS)

Interventions
Group 1: Emotional and social mind training (ESM) -
Patients in this group will receive a 17-session treatment (4 individual sessions, 12 group sessions, 1 follow-up session). The individual sessions will be used to develop an individual case formulation. The 12 group sessions will address:
1. Identification and understanding of inter- and intra-personal emotions
2. The social context of emotions
3. Managing intense and overwhelming emotions
4. Managing shame through compassionate mind training

The follow-up session will be a 'booster' for the group. Sessions will take place on a weekly basis. Individual sessions will be 60 and group sessions 90 minutes in length. Group sessions will include eight patients and be facilitated by two therapists. Overall, treatment will last 3 - 4 months.

Group 2: Group CBT programme -
Patients in this group will receive a 17-session group-based cognitive behavioural therapy treatment (4 individual sessions, 12 group sessions, 1 follow-up session). As with the ESM group, the individual sessions will be used to develop an individual case formulation. The timescales and group makeup will be identical to those of the ESM group.

Research assessments will take place at baseline, 4 months (end of treatment) and 6 months (follow-up). Severity of core bulimic symptoms (bingeing, purging, etc.) will be assessed using the Eating Disorders Examination. The following questionnaires/tests will also be used:
1. Depression Anxiety Stress Scale (DASS-21)
2. Levels of Self-Criticism Scale (LOSC)
3. Distress Tolerance Scale (DTS)
4. Beliefs About Emotions Questionnaire
5. Submissive Behaviour Scale (SBS)
6. Rumination Subscale of the Response Style Questionnaire (RSQ)
7. Clinical Impairment Assessment Questionnaire (CIA)
8. Participant satisfaction, assessed using Visual Analogue Scales

Social cognition tasks:
9. Reading the Mind from the Eyes Test
10. Reading the Mind in Films Task
11. Interpersonal Perception Task-15 (IPT-15)

Neuropsychological tests:
12. The National Adult Reading Test (NART)
13. D2 Brickenkamp Letter Cancellation Task (d2)
14. Rewarded Continuous Performance Task
15. Go/No-go task
16. Stroop colour word task
17. Game of dice task

Intervention Type
Behavioural

Primary outcome(s)
Core bulimic symptomology (bingeing, purging, etc.) measured by the Eating Disorders Examination (EDE) at baseline (pre-treatment), 4 months (end of treatment) and 6 months (follow-up).

Key secondary outcome(s)
1. Symptoms of depression, anxiety and stress, respectively, measured by the Depression Anxiety and Stress Scales (DASS-21). 21 items, each scored 0 - 3, giving total score of 0 - 63. Comprised of 3 scales (7 items each) for depression, anxiety and stress scoring 0 - 21, respectively. For each item score represents 0 (no symptom at all), 1 (symptom present to some degree, or some of the time), 2 (symptom present to considerable degree, or good part of the time), 3 (symptom present very much, or most of the time). Completed at pre-treatment, end of treatment (4 months) and follow-up (6 months).
2. Negative self-evaluation (comparative self-criticism and internalised self-criticism) measured by the Levels of Self-Criticism Scale (LOSC). 22 items, each scored 1 - 7 (strongly disagree to strongly agree), giving a total score of 22 - 154. Completed at pre-treatment, end of treatment (4 months) and follow-up (6 months).
3. Means of coping with negative mood and regulating emotional state measured by the Distress Tolerance Scale (DTS). 20 items, each scored 1 - 5 (never to all the time), giving a total score of 20 - 100. Completed at pre-treatment, end of treatment (4 months) and follow-up (6 months).
4. Beliefs about expressing emotions, coping with emotions and validity of emotions measured by the Beliefs About Emotions Questionnaire. 12 items, for each score 1 - 7 (totally agree to totally disagree). Completed at pre-treatment, end of treatment (4 months) and follow-up (6

months).
5. Submissive behaviour measured by the Submissive Behaviour Scale (SBS). 16 items, measured on scale 0 - 4 (0 = never, 1 = rarely, 2 = sometimes, 3 = mostly, 4 = always), giving total score 0 - 64. Completed at pre-treatment, end of treatment (4 months) and follow-up (6 months).
6. Ruminative Response Style Scale of the response Styles Questionnaire (RSQ). 22 items, measured on scale 0 - 4 (0 = never, 1 = rarely, 2 = sometimes, 3 = mostly, 4 = always), giving total score 0 - 88. Completed at pre-treatment, end of treatment (4 months) and follow-up (6 months).
7. Clinical Impairment Assessment Questionnaire (CIA), a 16-item self-report measure of the severity of psychosocial impairment due to eating disorder features. Each item scored 0 - 3, with a higher rating indicating a higher level of impairment. Completed at pre-treatment, end of treatment (4 months) and follow-up (6 months).
8. Participant satisfaction will be measured using visual analogue scales
9. Social cognition measured by Reading the Mind from the Eyes Test. 36 items, score 0 - 36. Completed at pre-treatment, end of treatment (4 months) and follow-up (6 months).
10. A more complex form of social cognition measured by the 'Reading the Mind in the Films task' (RMF). 22 items, score 0 - 22. Completed at pre-treatment, end of treatment (4 months) and follow-up (6 months).
11. Social perception measured by the Interpersonal Perception Task-15 (IPT-15). 15 items, score 0 - 15. Completed at pre-treatment only.
12. Premorbid levels of intelligence as estimated by the National Adult Reading Test (NART). Completed at pre-treatment only.
13. Selective attention/concentration measured by the D2 Brickenkamp Letter Cancellation Task (d2). Completed at pre-treatment, end of treatment (4 months) and follow-up (6 months).
14. Sustained attention and the effect of reward upon it, measured by the Rewarded Continuous Performance Task. Completed at pre-treatment, end of treatment (4 months) and follow-up (6 months).
15. Motor response inhibition measured by the Go/NoGo task. Completed at pre-treatment, end of treatment (4 months) and follow-up (6 months).
16. Concentration and speed of information processing measured by the Stroop colour word task. Completed at pre-treatment, end of treatment (4 months) and follow-up (6 months).
17. Decision-making measured by the Game of dice task. Completed at pre-treatment, end of treatment (4 months) and follow-up (6 months).

Completion date
20/10/2009

Eligibility

Key inclusion criteria
1. Patients referred to the South London and Maudsley Eating Disorder Service who fully (bulimia nervosa [BN]) or partially (eating disorder not otherwise specified [EDNOS]) fulfil Diagnostic and Statistical Manual of Mental Disorders, 4th Edition (DSM-IV) criteria for bulimia nervosa
2. Outpatients
3. Male or female
4. Aged 18 - 65 years

Participant type(s)
Patient

Healthy volunteers allowed

No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Insufficient knowledge of English or literacy levels to allow understanding of the intervention materials
2. Active suicidality
3. Severe substance dependence
4. Diabetes
5. Pregnancy
6. Received Maudsley Model treatment for eating disorder within last 12 months

Date of first enrolment
20/04/2009

Date of final enrolment
20/10/2009

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Institute of Psychiatry
London
United Kingdom
SE5 8AF

Sponsor information

Organisation
Institute of Psychiatry (UK)

ROR

https://ror.org/0220mzb33

Funder(s)

Funder type
Research organisation

Funder Name
Swiss Anorexia Nervosa Foundation (Switzerland)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/10/2012		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes